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Date March 29, 1999

John P. Parise  
(Print Name)

(Signature)

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Binggeli et al.

Group: 1613

Serial No. 08/711,339, filed September 6, 1996

Examiner: R. Ramseur

For: **NOVEL PIPERIDINE DERIVATIVES HAVING RENIN INHIBITING ACTIVITY**

**RENEWED PETITION TO COMMISSIONER UNDER 37 C.F.R. §1.144**

Nutley, New Jersey 07110  
March 29, 1999

Assistant Commissioner for Patents  
Washington, D.C. 20231  
Attn: Group Director

Sir:

This Renewed Petition is filed in response to the February 3, 1999 Petition Decision issued in connection with the above-identified patent application. The period for timely filing this Renewed Petition expires April 3, 1999.

Applicants request that the Group Director direct the Examiner to examine claim 1, as written, in accordance with Patent Office procedure and the law. It is applicants' position that even if the restriction requirement *per se* were proper, the Patent Office does not have the authority to require applicants to amend their claim in order for such claim to be considered in its entirety on the merits. The Group Director has the authority to decide this Petition [MPEP 1002.02(c)(3)].

Claims 1-40 and 42-137 are pending in the subject application. Portions of claims 1-17, 20, 32, 33, 35-39, 42-45, 47, 68-72, 74, 77, 87-90, and all of claims 18, 19, 21-31, 34, 46, 48-67, 73, 75, 76, 79-86, and 91-136, have been withdrawn from further consideration under 37 C.F.R. § 1.142(b) because they are allegedly drawn to non-elected inventions. Claims 40, 78, and 137 have been objected to as being dependent upon a non-allowed claim. An appeal brief was filed with the Board of Patent Appeals and Interferences on February 22, 1999 because the Patent Office's action tantamount to a rejection.

In an October 16, 1997 Office Action, the Patent Office issued what was believed by applicants to be an election requirement. In their Amendment dated November 7, 1997, applicants elected a single species for examination purposes, i.e. the compound of claim 137, (3R,4S,5S)-3-(1,4-dimethoxy-naphthalen-2-ylmethoxy)-4-[4-[3-(2-methoxy-

benzyloxy)-propoxy]-phenyl]-piperidin-5-ol. In response, the Patent Office in its March 23, 1998 Office Action identified a "generic concept" which was created by the Patent Office to encompass applicants' claimed species. In the most recent Office Action, the Patent Office made final its restriction requirement that presumably restricts the claimed compounds into two groups: (1) the "generic concept" and (2) all other compounds. However, in view of the "generic concept" approach, it is uncertain whether the second group contains one or many allegedly independent inventions.

On November 11, 1998, applicants filed a Petition requesting that the restriction requirement be withdrawn. The Petition was denied in a February 3, 1999 Petition Decision. The Petition Decision provides reasons for upholding the restriction requirement but provides no legal reasoning as to why *In re Weber*, 198 USPQ 328 (CCPA 1978) should not be applied. Rather, the Patent Office has continued to maintain an intraclaim restriction requirement based on 35 U.S.C. §121. No rejection has been made on the merits.<sup>1</sup>

The Patent Office has no legal authority to create a "generic concept" and require applicants to limit a particular claim to the subject matter indicated as being allowable, i.e.

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<sup>1</sup> The phrase "on the merits" includes 35 U.S.C. §100, 101, 102, 103, and 112. See *In re Hamisch*, 206 U.S.P.Q. 300, 304 (CCPA 1980).

claim 1 as limited to embrace the generic concept.<sup>2</sup> Even the Petition Decision acknowledged that "[a]pplicants are correct in this area."

The Petition Decision goes on to suggest that "applicants did not offer any suggestions as to proper genus or argue that the genus determined by the examiner was improper except with respect to the entire scope of claim 1." This is incorrect. First, applicants have no obligation to make suggestions as to what constitutes a proper genus (applicants' position is that claim 1 claims a proper genus). Second, applicants did in fact make numerous suggestions during an interview with the Examiner on June 24, 1998. However, no agreement was reached.

Procedures for making an election of species are described in MPEP 809.02. Applicants made a species election in response to this Office Action. As set forth in MPEP 809.02, the Patent Office is required to perform a search for all claims readable on the elected species, including applicants' claim 1 in the present situation. The MPEP does not authorize the Patent Office to derive "a generic concept as depicted in claim 1" to be carved out of existing claims. As stated in the Petition Decision (quoting M.P.E.P. 803.02) "the examiner may require a provisional election of a single species

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<sup>2</sup> The "generic concept" refers to the subject matter of claim 1 limited to where R<sup>1</sup> is aryl optionally substituted by lower alkyl, lower alkenyl, trifluoromethyl, lower alkoxy, hydroxy-lower alkoxy, alkoxy-alkoxy; R<sup>2</sup> is phenyl or naphthyl each substituted by -O-C<sub>1-8</sub> alkylene or -O-C<sub>1-8</sub> alkylene-aryl wherein aryl

.... [t]he Markush-type claim would then be examined fully with respect to the elected species ..... should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended." This has not occurred in the present application. Therefore, the Patent Office has not followed its own internal procedures.

The real question at issue is whether 35 U.S.C. §121 gives the Patent Office authority to create a "generic concept" inclusive of a species elected by applicant and require applicant to amend a single claim embracing the "generic concept" so as to only encompass the "generic concept" in order for that single claim to be examined and considered on the merits.<sup>2</sup> It is applicants' position that the Patent Office does not have this authority. The Patent Office must examine a single claim in its entirety and either allow or reject such claim.

Applicants have the right under U.S. patent law to claim their invention using the limitations that they regard as essential to delineate the invention, as long as the requirements of 35 U.S.C. §112 are met. It is well-established law that restriction within a single claim cannot be sustained under 35 U.S.C. §121. As is stated in *Weber*, at pages 331-332,

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is as defined for R<sup>1</sup>; X is O, S; Z is lower alkylene; Q is absent; m is O (W is absent); R<sup>3</sup> is hydrogen; R<sup>4</sup> is

"§121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It is not, however, provide a basis for the Examiner acting under the authority of the Commissioner to *reject a particular claim* on that same basis." (Emphasis in original text.)

In the subject application, the Patent Office made the exact type of restriction requirement expressly forbidden by the CCPA in *Weber*. Such restriction is tantamount to a rejection. See *In re Hass*, 179 USPQ 623 (CCPA 1973). There is no basis under 35 U.S.C. §121 to restrict claim 1 and the subsequent generic claims encompassing the species of claim 137 in the manner set forth by the Patent Office.

Applicants find nothing in 35 U.S.C. §121 that gives the Patent Office legal authority to create a "generic concept" and require applicants to amend a particular claim so as to only claim the subject matter indicated as being allowable, i.e. claim 1 as limited to embrace the generic concept.<sup>3</sup> The Petition Decision agrees with this point, yet does not require the Examiner to consider claim 1 in its entirety on the merits.

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OH.

<sup>3</sup> The "generic concept" refers to the subject matter of claim 1 limited to where R<sup>1</sup> is aryl optionally substituted by lower alkyl, lower alkenyl, trifluoromethyl, lower alkoxy, hydroxy-lower alkoxy, alkoxy-alkoxy; R<sup>2</sup> is phenyl or naphthyl each substituted by -O-C<sub>1-8</sub> alkylene or -O-C<sub>1-8</sub> alkylene-aryl wherein aryl is as defined for R<sup>1</sup>; X is O, S; Z is lower alkylene; Q is absent; m is O (W is absent); R<sup>3</sup> is hydrogen; R<sup>4</sup> is OH.

As in *Hass*, the claims in the present application are being withdrawn from consideration not only in this application but also prospectively in any subsequent application because of their content. As the Patent Office's "generic concept" is constructed, it would be impossible for applicants to garner in subsequent patent applications the remainder of the claims after the "generic concept" is cleaved out<sup>4</sup>, especially with regard to the written description requirement.

If the Patent Office is permitted to create a "generic concept", numerous issues arise as to who is the inventor of the "generic concept"? and does the specification provide a written description of the "generic concept"? Although every species contained within the "generic concept" would be enabled by the specification, the "generic concept" *per se* could lack a written description in the specification as filed.

This is the exact situation envisioned in *Weber* which states on page 331:

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the sub-genera would be defined by the examiner rather than the applicant, it is not inconceivable that a number of the fragments would not be described by the specification.

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<sup>4</sup> Applicants note that the Patent Office did not provide a number of distinct categories under into which the compounds of claim 1 could be divided, but rather, created a "generic concept". Applicants, therefore, could not predict the number of divisional applications that are being requested by the Patent Office.

The Petition Decision addresses *Weber* merely saying that the "argument is specious in this particular situation since it would be beyond an examiner's and the Office's skill, resources, time and expertise to consider a claim to over 11 quadrillion (11,000,000,000,000,000) compounds." While such statement may be true under certain conditions, it is clearly not the law. If anything, applicants' claim 1 would be more subject to the fragmentary claim problem foreseen in *Weber*.

The law does not support the "generic concept" approach. The law requires the Patent Office to either allow or reject a claim that reads upon an elected species.

In view of the above, applicants request that all claims containing applicants' elected species be considered on the merits since such consideration is required both under the law and under Patent Office policy as set forth in the MPEP.

For completeness, applicants request that on remand the Examiner consider documents A2, A3, B2 and B3 and initialed Forms 1449 be returned to applicants.

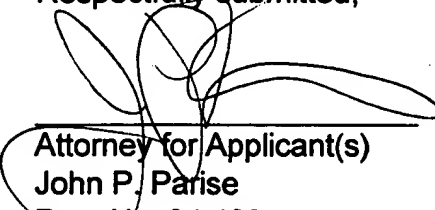
Grant of this Renewed Petition is earnestly solicited.



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No fee is required in connection with the filing of this Renewed Petition. If any fee is deemed necessary, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

A handwritten signature in black ink, appearing to be "John P. Parise", written over a horizontal line.

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